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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,646	03/24/2005	Takaaki Terahara	7388/84281	8337

42798 7590 09/05/2007

FITCH, EVEN, TABIN & FLANNERY
P. O. BOX 18415
WASHINGTON, DC 20036

EXAMINER	
SASAN, ARADHANA	
ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
09/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,646	TERAHARA ET AL.	
	Examiner	Art Unit	
	Aradhana Sasan	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/25/05, 3/18/05, and 6/19/07*.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

DETAILED ACTION

Status of Application

1. The remarks filed on 06/19/2007 are acknowledged.

2. Claims 1-6 are included in the prosecution.

Priority

3. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Information Disclosure Statement

4. The information disclosure statements (IDS) submitted on 2/25/05, 3/18/05, and 6/19/07 were filed. The submissions are in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statements.

See attached copy of PTO-1449.

Response to Arguments

Rejection of claims 1-6 under 35 USC § 103(a)

5. Applicant's arguments with respect to the rejection of claims 1-6 under 35 USC § 103(a) as being unpatentable over Hirano et al. (US 6,495,159) in view of Terahara et al. (US 2004/0028724 A1) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground of rejection is made in view of newly found prior art Higo et al. (US 5,866,157) in view of Arth et al. (US 6,461,636).

6. Additionally, rejections under non-statutory obviousness type double patenting are also being made.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Higo et al. (US 5,866,157) in view of Arth et al. (US 6,461,636).

The claimed invention is a patch comprising a backing layer and an adhesive layer that is disposed on the backing layer. The adhesive layer is compounded with a drug and an adhesive base agent. The adhesive base agent comprises: (i) styrene-isoprene-styrene block copolymer, (ii) 2-ethylhexyl acrylate-vinyl acetate copolymer, and (iii) a basic nitrogen-including polymer, which includes a basic nitrogen and has no adhesion property at normal temperature.

Higo teaches a matrix type patch formulation which comprises an adhesive layer containing a physiological active substance, an organic acid, a hydrophobic high molecular material, a tackifying resin, a plasticizer and an absorption enhancer (Abstract). Organic acids such as acetic acid are disclosed as being used in the adhesive layer of the patch (Col. 2, lines 62-64). The physiological active substance in the adhesive layer includes agents for Parkinson's disease (Col. 3, lines 36-37). Styrene-isoprene-styrene block copolymer is disclosed as the hydrophobic high

molecular material in the adhesive layer of the patch (Col. 3, lines 64-67). Acrylic polymer "(copolymer of at least two materials selected from the group comprising 2-ethylhexyl acrylate, vinyl acetate, methacrylate, methoxyethyl acrylate and acrylic acid)" is disclosed as being formulated in the adhesive layer of the patch (Col. 4, lines 4-8). Alicyclic saturated hydrocarbon resins are disclosed as the tackifying resin formulated in the adhesive layer of the patch (Col. 4, lines 19-25).

Higo does not expressly teach the drug pergolide as part of the adhesive layer of the patch formulation.

Arth teaches a transdermal therapeutic system (TTS) containing pergolide. A TTS including "a matrix mass containing pergolide and taking the form of a layer, the matrix mass containing a (meth)acrylate copolymer containing ammonio groups or a mixture of a (meth)acrylate copolymer containing amino groups ..." is disclosed (Col. 5, lines 3-8). Examples include the physiologically active substance pergolide mesilate and Eudragit® polymers as the methacrylate copolymers (Col. 6, line 45 to Col. 7, line 41).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a transdermal patch formulation, which comprises an adhesive layer containing a physiological active substance (including those for Parkinson's disease), an organic acid, a hydrophobic high molecular material (styrene-isoprene-styrene block copolymer), an acrylic polymer (copolymer of at least two materials selected from the group comprising 2-ethylhexyl acrylate, vinyl acetate, methacrylate, methoxyethyl acrylate and acrylic acid), and alicyclic saturated hydrocarbon resins as the tackifying resin, as suggested by Higo, and combine it with

the transdermal therapeutic system containing pergolide, as suggested by Arth, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Arth teaches that "the transcutaneous administration of pergolide by means of a TTS is desirable since, by bypassing the gastrointestinal tract and the first passage through the liver, concentration peaks of pergolide in the blood, which can lead to the occurrence of undesirable effects, ... are avoided" (Col. 4, lines 45-50).

Regarding instant claim 1, the limitation of a patch with a backing layer and an adhesive layer with the drug and adhesive base agent would have been obvious to one skilled in the art over the patch formulation which comprises an adhesive layer containing a physiological active substance taught by Higo. The limitation of the styrene-isoprene-styrene block copolymer would have been obvious over the styrene-isoprene-styrene block copolymer taught by Higo. The limitation of the 2-ethylhexyl acrylate-vinyl acetate copolymer would have been obvious over the copolymer of at least two materials selected from the group comprising 2-ethylhexyl acrylate, vinyl acetate, methacrylate, methoxyethyl acrylate and acrylic acid taught by Higo.

The limitation of the basic nitrogen-including polymer, which includes a basic nitrogen and has no adhesion property at normal temperature of instant claims 1 and 2, would have been obvious over the Eudragit® polymers as the methacrylate copolymers taught by Arth.

Regarding instant claims 3-4, the limitation of the solubility of the drug and drug selection would have been obvious to one skilled in the art over the pergolide mesilate

in a patch formulation taught by Arth. Since the property of solubility is intrinsically associated with the particular drug, the use of pergolide mesilate as disclosed by Arth renders obvious the solubility limitation.

Regarding instant claim 5, the limitation of the adhesive layer further comprising an organic acid would have been obvious to one skilled in the art over organic acids such as acetic acid disclosed as being used in the adhesive layer of the patch by Higo.

Regarding instant claim 6, the limitation of the adhesive layer further comprising an alicyclic saturated hydrocarbon resin would have been obvious to one skilled in the art over the alicyclic saturated hydrocarbon resin used as the tackifying resin in the adhesive layer of the patch as taught by Higo.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-2 and 4-6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 10/526,065 ('065 hereinafter). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a patch comprising a backing layer and an adhesive layer that is compounded with a drug and an adhesive base agent. The adhesive base agent comprises styrene-isoprene-styrene block copolymer, 2-ethylhexyl acrylate-vinyl acetate copolymer and a basic nitrogen-including polymer, which is selected from methyl acrylate-butyl methacrylate-dimethylaminoethyl methacrylate and polyvinyl acetal diethylamino acetate. The drug is selected from a group containing pergolide. The adhesive layer also comprises an organic acid and an alicyclic saturated hydrocarbon-based tackifier.

Claims 1-11 of '065 are also drawn to a patch comprising a backing layer and an adhesive layer compounded with an adhesive base agent and pergolide. The adhesive base agent comprises an acrylic polymer, a basic nitrogen-including polymer selected from methyl methacrylate-butyl methacrylate-dimethylaminoethyl methacrylate terpolymer and polyvinyl acetal diethylamino acetate. The adhesive layer also comprises an alicyclic saturated hydrocarbon resin-based tackifier. 2-ethylhexyl acrylate-vinyl acetate copolymer is claimed as an acrylic polymer and styrene-isoprene-styrene block copolymer is claimed as the rubber polymer. The adhesive layer also contains an organic acid (acetic acid and/or a pharmaceutically acceptable salt).

The difference between the instant claims and those of '065 is that claims of '065 include the limitation of the weight ratio of the content of the acrylic polymer to the content of the rubber polymer and the weight ratio of the content of the acrylic polymer and the rubber polymer to the content of the basic nitrogen-including polymer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the ratio of the content of the acrylic polymer to the content of the rubber polymer and the weight ratio of the content of the acrylic polymer and the rubber polymer to the content of the basic nitrogen-including polymer during the process of routine experimentation in order to achieve optimal skin absorption of the drug.

The instant claims are obvious over the claims of '065 and thus they are not patentably distinct over each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

11. Due to the new grounds of rejection, this action is made non-final.

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600